

What Is Claimed Is:

1. An adjuvant composition comprising GAP-DMORIE and one or more co-lipids.
- 5 2. The adjuvant composition of claim 1 wherein the co-lipid is a neutral lipid.
3. The adjuvant composition of claim 1 wherein the co-lipid is a phosphatidylethanolamine.
4. The adjuvant composition of claim 3 wherein the phosphatidylethanolamine is selected from the group consisting of DOPE, DPyPE, and DMPE.
- 10 5. The adjuvant composition of claim 4 wherein the phosphatidylethanolamine is DOPE.
6. The adjuvant of claim 4 wherein the phosphatidylethanolamine is DPyPE.
7. The adjuvant of claim 1 wherein the GAP-DMORIE and the co-lipid are in molar ratio of from about 9:1 to about 1:9.
- 15 8. The adjuvant of claim 1 wherein the GAP-DMORIE and the co-lipid are in molar ratio of from about 4:1 to about 1:4.
9. The adjuvant of claim 1 wherein the GAP-DMORIE and the co-lipid are in molar ratio of from about 2:1 to about 1:2.
10. The adjuvant of claim 1 wherein the GAP-DMORIE and the co-lipid are in molar ratio of about 1:1.
- 20 11. The adjuvant of claim 6 wherein the GAP-DMORIE and DPyPE are in molar ratio of from about 2:1 to about 1:2.
12. The adjuvant of claim 6 wherein the GAP-DMORIE and DPyPE are in molar ratio of about 1:1.
- 25 13. An immunogenic composition comprising an immunogen and an adjuvant composition comprising GAP-DMORIE and one or more co-lipids.
14. The immunogenic composition of claim 13 wherein the immunogen comprises an immunogen-encoding polynucleotide.
15. The immunogenic composition of claim 14 wherein the immunogen-encoding polynucleotide is DNA, RNA, or nucleic acid oligomer.
- 30

16. The immunogenic composition of claim 14 wherein the immunogen-encoding polynucleotide is a linear or circular polynucleotide.
17. The immunogenic composition of claim 14 wherein the immunogen-encoding polynucleotide is all or part of a plasmid DNA.
- 5 18. The immunogenic composition of claim 14 wherein the co-lipid is selected from the group consisting of DOPE, DPyPE, and DMPE.
19. The immunogenic composition of claim 18 wherein the co-lipid is DOPE.
20. The immunogenic composition of claim 18 wherein the co-lipid is DPyPE.
21. The immunogenic composition of claim 14 wherein the GAP-DMORIE and
10 the co-lipid are in molar ratio of from about 9:1 to about 1:9.
22. The immunogenic composition of claim 14 wherein the GAP-DMORIE and the co-lipid are in molar ratio of from about 4:1 to about 1:4.
23. The immunogenic composition of claim 14 wherein the GAP-DMORIE and the co-lipid are in molar ratio of from about 2:1 to about 1:2.
- 15 24. The immunogenic composition of claim 14 wherein the GAP-DMORIE and the co-lipid are in molar ratio of about 1:1.
25. The immunogenic composition of claim 20 wherein the GAP-DMORIE and DPyPE are in molar ratio of from about 2:1 to about 1:2.
26. The immunogenic composition of claim 20 wherein the GAP-DMORIE and
20 DPyPE are in molar ratio of about 1:1.
27. A method for immunizing a vertebrate comprising administering into a tissue or cavity of said vertebrate an immunogenic composition comprising one or more immunogen-encoding polynucleotide and an adjuvant composition comprising GAP-DMORIE, wherein an immunogen is expressed in the vertebrate in an amount
25 sufficient to generate an immune response to the immunogen.
28. The method of claim 27 wherein the immunogenic composition further comprises one or more co-lipids.
29. The method of claim 28 wherein the immunogen-encoding polynucleotide is DNA, RNA, or nucleic acid oligomer.

30. The method of claim 28 wherein the immunogen-encoding polynucleotide is all or part of a plasmid DNA.
31. The method of claim 28 wherein the co-lipid is selected from the group consisting of DOPE, DPyPE, and DMPE.
- 5 32. The method of claim 28 wherein the co-lipid is DOPE.
33. The method of claim 28 wherein the co-lipid is DPyPE.
34. The method of claim 28 wherein the GAP-DMORIE and the co-lipid are in molar ratio of from about 9:1 to about 1:9.
35. The method of claim 28 wherein the GAP-DMORIE and the co-lipid are in
10 molar ratio of from about 4:1 to about 1:4.
36. The method of claim 28 wherein the GAP-DMORIE and the co-lipid are in molar ratio of from about 2:1 to about 1:2.
37. The method of claim 28 wherein the GAP-DMORIE and the co-lipid are in molar ratio of about 1:1.
- 15 38. The method of claim 33 wherein the GAP-DMORIE and DPyPE are in molar ratio of from about 2:1 to about 1:2.
39. The method of claim 33 wherein the GAP-DMORIE and DPyPE are in molar ratio of about 1:1.
40. The method of claim 27 wherein the vertebrate is a mammal.
- 20 41. The method of claim 40 wherein the mammal is a human.
42. The method of claim 28 wherein the immunogenic composition is a pharmaceutical composition.
43. The method of claim 28 wherein said immunogen is selected from the group consisting of a bacterial polypeptide, a fungal polypeptide, a parasite polypeptide, an
25 allergenic polypeptide, a tumor specific polypeptide, an immunogenic fragments, derivatives, or analogs thereof.
44. The method of claim 28 wherein said tissue is selected from the group consisting of muscle, skin, brain tissue, lung tissue, liver tissue, spleen tissue, bone marrow tissue, thymus tissue, heart tissue, lymph tissue, blood tissue, bone tissue,
30 connective tissue, mucosal tissue, pancreas tissue, kidney tissue, gall bladder tissue,

stomach tissue, intestinal tissue, testicular tissue, ovarian tissue, uterine tissue, vaginal tissue, rectal tissue, nervous system tissue, eye tissue, glandular tissue, and tongue.

45. The method of claim 28 wherein said cavity is selected from the group consisting of lung, mouth, nasal cavity, stomach, peritoneum, intestine, heart
5 chamber, vein, artery, capillary, lymphatic, uterus, vagina, rectum, and ocular cavity.

46. The method of claim 28, wherein said cavity comprises a mucosal surface.

47. The method of claim 28, wherein said tissue is muscle.

48. The method of claim 47, wherein said tissue is skeletal muscle.

49. The method of claim 28, wherein said administration is intravenous.

10 50. The method of claim 28, wherein said administration is by a route selected from the group consisting of intramuscular, intratracheal, intranasal, transdermal, interdermal, subcutaneous, intraocular, vaginal, rectal, intraperitoneal, intrainestinal and inhalation.

15 51. The method of any one of claim 28, wherein said administration is mediated by a device selected from the group consisting of a particle accelerator, a pump, an intradermal applicator, a biolistic injector, a pneumatic injector, a sponge depot, a pill and a tablet.

52. The method of claim 28, wherein said administration is mediated by a Biojector®2000.

20 53. A method for providing a mammal a prophylactic or therapeutic treatment associated with a bacterial infection comprising

administering to the mammal an immunogenic composition comprising one or more immunogen-encoding polynucleotides associated with the bacterial infection and an adjuvant composition comprising GAP-DMORIE and a co-lipid, wherein an
25 immunogen is expressed in the mammal in an amount sufficient to generate an immune response to the immunogen.

54. The method of claim 53 wherein the co-lipid is DPyPE.

55. A method for providing a mammal a prophylactic or therapeutic treatment associated with a viral infection comprising

administering to the mammal an immunogenic composition comprising one or more immunogen-encoding polynucleotides associated with the viral infection and an adjuvant composition comprising GAP-DMORIE and a co-lipid, wherein an immunogen is expressed in the mammal in an amount sufficient to generate an immune response to the immunogen.

56. The method of claim 55 wherein the co-lipid is DPyPE.

57. A method for providing a mammal a prophylactic or therapeutic treatment associated with an abnormal growth of a cell population comprising

administering to the mammal an immunogenic composition comprising one or more immunogen-encoding polynucleotides associated with the abnormal growth of the cell population and an adjuvant composition comprising GAP-DMORIE and a co-lipid, wherein an immunogen is expressed in the mammal in an amount sufficient to generate an immune response to the immunogen.

58. The method of claim 57 wherein the abnormal growth of a cell population is associated with cancer.

59. The method of claim 58 wherein the co-lipid is DPyPE.

60. A pharmaceutical kit comprising:

(a) a container holding 1ng to 30 mg of an immunogen-encoding polynucleotide which operably encodes an immunogen within vertebrate cells in vivo; and

(b) an adjuvant composition comprising GAP-DMORIE and a co-lipid, whereby said immunogen is provided in a prophylactically or therapeutically effective amount to treat a vertebrate.

61. The pharmaceutical kit of claim 60, wherein (b) is in the container of (a).

62. The pharmaceutical kit of claim 60, wherein (b) is in the separate container from (a).

63. The pharmaceutical kit of claim 60, further comprising an administration means.

64. The pharmaceutical kit of claim 60, wherein said co-lipid is DPyPE.

65. The pharmaceutical kit of claim 64, wherein said GAP-DMORIE and DPyPE are in molar ratio of about 2:1 to about 1:2.

66. The pharmaceutical kit of claim 64, wherein said GAP-DMORIE and DPyPE are in molar ratio of about 1:1.

⁵ add B' >

009260 1092600